



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:  
David Yang *et al.*

Serial No.: 09/599,152

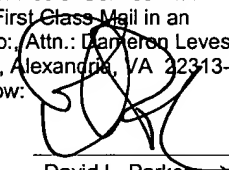
Filed: June 21, 2000

For: ETHYLENEDICysteINE (EC)-DRUG  
CONJUGATES, COMPOSITIONS AND  
METHODS FOR TISSUE SPECIFIC  
DISEASE IMAGING

Group Art Unit: 1645

Examiner: Dameron Levest Jones

Atty. Dkt. No.: UTSC:664

CERTIFICATE OF MAILING 37 C.F.R. 1.8	
I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Attn.: Dameron Levest Jones, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below:	
March 29, 2004	
Date	David L. Parker

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Attn.: Dameron Levest Jones  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Sir:

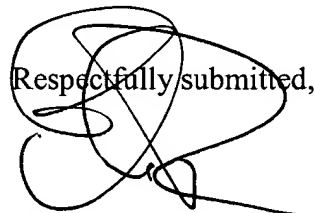
In compliance with the duty of disclosure under 37 C.F.R. § 1.56, it is respectfully requested that this Supplemental Information Disclosure Statement be entered and the documents listed on attached Form PTO-1449 be considered by the Examiner and made of record. Copies of the listed documents required by 37 C.F.R. § 1.98(a)(2) are enclosed for the convenience of the Examiner.

In accordance with 37 C.F.R. §§ 1.97(g), (h), this Supplemental Information Disclosure Statement is not to be construed as a representation that a search has been made, and is not to be

construed to be an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

A fee as set forth in 37 C.F.R. § 1.17(p) in the amount of \$180.00 is enclosed herewith. If an appropriate check has not been enclosed, or if it is insufficient, the Commissioner is authorized to deduct the appropriate fee from Fulbright & Jaworski Account No.: 50-1212/UTSC:664.

Applicants respectfully request that the listed documents be made of record in the present case.

Respectfully submitted,  


David L. Parker  
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Attorney for Applicants

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Date: March 29, 2004

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List of Patents and Publications for Applicant's

INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)

Applicants

David Yang, Chun-Wei Liu, Dong-Fang Yu and E.  
Edmund Kim

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## U.S. Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Name	Class	Sub Class	Filing Date of App.
	A14	2001/0034363	10/25/01	Li <i>et al.</i>	514	449	3/30/98
	A15	2001/0041189	11/15/01	Xu	424	488	4/13/99
	A16	4,418,068	11/29/83	Jones	424	267	12/16/81
	A17	4,507,466	3/26/85	Tomalia <i>et al.</i>	528	332	1/07/83
	A18	4,558,120	12/10/85	Tomalia <i>et al.</i>	528	363	12/27/83
	A19	4,568,737	2/04/86	Tomalia <i>et al.</i>	528	332	8/17/84
	A20	4,587,329	5/06/86	Tomalia <i>et al.</i>	528	363	7/19/85
	A21	4,631,337	12/23/86	Tomalia <i>et al.</i>	528	391	7/11/85
	A22	4,694,064	9/15/87	Tomalia <i>et al.</i>	528	332	2/28/86
	A23	4,713,975	12/22/87	Tomalia <i>et al.</i>	73	864.8	5/30/86
	A24	4,732,863	3/22/88	Tomasi <i>et al.</i>	436	547	12/31/84
	A25	4,737,550	4/12/88	Tomalia	525	419	12/08/86
	A26	4,857,599	8/15/89	Tomalia <i>et al.</i>	525	259	2/08/88
	A27	4,871,779	10/03/89	Killat <i>et al.</i>	521	28	12/23/85
	A28	5,087,616	2/11/92	Myers <i>et al.</i>	514	21	8/06/87
	A29	5,164,294	11/17/92	Skold <i>et al.</i>	435	7.5	7/07/89
	A30	5,412,072	5/02/95	Sakurai <i>et al.</i>	530	322	3/21/90
	A31	5,534,241	7/09/96	Torchilin <i>et al.</i>	424	9.321	7/23/93
	A32	5,605,671	2/25/97	Lyle <i>et al.</i>	424	1.41	4/29/94
	A33	5,635,603	6/03/97	Hansen <i>et al.</i>	530	391.5	12/05/94
	A34	5,670,132	9/23/97	Griffiths <i>et al.</i>	424	1.11	9/20/94
	A35	5,830,431	11/03/98	Srinivasan <i>et al.</i>	424	1.69	6/07/95
	A36	5,908,777	6/01/99	Lee <i>et al.</i>	435	320.1	3/23/95

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INFORMATION DISCLOSURE STATEMENT — PTO-1449 (MODIFIED)



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	A37	5,977,163	11/02/99	Li <i>et al.</i>	514	449	3/11/97
	A38	6,071,533	6/06/00	Papahadjopoulos <i>et al.</i>	424	450	11/17/95
	A39	6,083,741	7/04/00	Hart <i>et al.</i>	435	320.1	11/17/95
	A40	6,113,946	9/05/00	Szoka, Jr. <i>et al.</i>	424	486	6/06/95
	A41	6,251,866	6/26/01	Prakash <i>et al.</i>	514	17	8/04/98
	A42	6,262,107	7/17/01	Li <i>et al.</i>	514	449	7/01/99
	A43	5,517,993	5/21/96	Unger and Wu	128	653.4	6/07/95

## Foreign Patent Documents

Exam. Init.	Ref. Des.	Document Number	Date	Country	Class	Sub Class	Translation Yes/No
	B1	WO 95/28966	11/02/95	PCT			
	B2	WO 97/33552	9/18/97	PCT			
	B3	WO 99/39748	8/12/99	PCT			
	B4	WO 99/49901	10/07/99	PCT			
	B5	WO 99/61512	12/02/99	PCT			
	B6	WO 00/53233	9/14/00	PCT			
	B7	WO 00/61788	10/19/00	PCT			

## Other Art (Including Author, Title, Date Pertinent Pages, Etc.)

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	C147	Anderson <i>et al.</i> , "Radiometal-labeled agents (non-technetium) for diagnostic imaging," <i>Chem. Rev.</i> , 99:2219-2234, 1999.
	C148	Antony, "Folate receptors," <i>Ann. Rev.</i> , 16:501-521, 1996.

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Exam. Init.	Ref. Des.	Citation
	C149	Aoi <i>et al.</i> , "Globular carbohydrate macromolecule 'sugar balls' 3. 'radical-growth polymerization' of sugar-substituted $\alpha$ -amino acid N-carboxyanhydrides (glycoNCAs) with a dendritic initiator," <i>Tetrahedron, Elsevier Science Publishers</i> , 53(45):15415-15427, 1997.
	C150	Bajorin <i>et al.</i> , <i>Proc. Annu. Meet. Am. Soc. Clin. Oncol.</i> , 7:250, A967, 1988.
	C151	Baselga <i>et al.</i> , "Phase I studies of anti-epidermal growth factor receptor cheimeric antibody C225 alone and in combination with cisplatin," <i>J. Clinical Oncology</i> , 18(4):904-914, 2000.
	C152	Baselga <i>et al.</i> , "Recombinant humanized anti-HER2 antibody (herceptin) enhances the antitumor activity of paclitaxel and doxorubicin against HER2/new overexpressing human breast cancer xenografts," <i>Cancer Research</i> , 58:2825-2831, 1998.
	C153	Benns <i>et al.</i> , "Tailoring new gene delivery designs for specific targets," <i>Journal of Drug Targeting</i> , 8(1), Database Medline on STN International, Accession No. 2000222278, 2 pages, 2000.
	C154	Blackenberg <i>et al.</i> , "Apoptosis: the importance of nuclear medicine," <i>Nucl. Med. Comm.</i> , 21:241-250, 2000.
	C155	Blackenberg <i>et al.</i> , "In vivo detection and imaging of phosphatidylserine expression during programmed cell death," <i>Proc. Natl. Acad. Sci., USA</i> , 95:6349-6354, 1998.
	C156	Blair <i>et al.</i> , "Linkage of cytotoxin agents to immunoglobulins," <i>Journal of Immunological Methods</i> , 59:129-143, 1983..
	C157	Block, "Poly(g-benzyl-L-glutamate) and other glutamic acid containing polymers," Gordon and Breach Science Publishers, New York, 11-31, 1983.
	C158	Bohdiewicz <i>et al.</i> , "Indium-111 satumomab pendetide: the first FDA-approved monoclonal antibody for tumor imaging," <i>J. Nuclear Medicine Technology</i> , 26(3):155-163, 1998.
	C159	Brechbiel <i>et al.</i> , "Synthesis of 1 (P-isothiocyanatobenzyl) derivatives of DTPA and EDTA: antibody labeling and tumor-imaging studies," <i>Inorg. Chem.</i> , 25:2772-2781, 1986.
	C160	Brogi <i>et al.</i> , "Hypoxia-induced paracrine regulation of vascular endothelial growth factor receptor expression," <i>J. Clin. Invest.</i> , 97(2):469-476, 1996.
	C161	Brokx <i>et al.</i> , "Designing peptide-based scaffolds as drug delivery vehicles," <i>Science</i> , 78(1-3):115-123, 2002.

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	C162	Budiardjo <i>et al.</i> , "Biochemical pathways of caspase activation during apoptosis," <i>Annu. Rev. Cell Dev. Biol.</i> , 15:269-290, 1999.
	C163	Burgen, "Targets of drug action," <i>Ann. Rev. Pharmacol. Toxicol.</i> , 40:1-16, 2000.
	C164	Chapman <i>et al.</i> , "Therapeutic antibody fragments with prolonged in vivo half-lives," <i>Nature Biotech.</i> , 17:780-783, 1999.
	C165	Collier <i>et al.</i> "Immunoscintigraphy performed with In-111-labeled CYT-103 in the management of colorectal cancer: comparison with CT," <i>Radiology</i> , 185:179-186, 1992.
	C166	Culver <i>et al.</i> , "In vivo gene transfer with retroviral vector-producer cells for treatment of experimental brain tumors," <i>Science</i> , 256:1550-1552, 1992.
	C167	Deguchi <i>et al.</i> , "Retention of biologic activity of human epidermal growth factor following conjugation to a blood-brain barrier drug delivery vector via an extended poly(ethylene glycol) linker," <i>Bioconjugate Chem.</i> , 10:32-37, 1999.
	C168	DeNardo <i>et al.</i> , "Pharmacokinetics of chimeric L6 conjugated to indium 111- and yttrium-90-DOTA-peptide in tumor-bearing mice," <i>J. Nuclear Medicine</i> , 36:829-836, 1995.
	C169	DeNardo <i>et al.</i> , "Yttrium-90/indium-111-DOTA-peptide-chimeric L6: Pharmacokinetics, dosimetry and initial results in patients with incurable breast cancer," <i>Anticancer Research</i> , 17(3B):1735-1744, 1997.
	C170	Deutsch <i>et al.</i> , "Synthesis of congeners and prodrugs, water-soluble prodrugs of taxol with potent antitumor activity," <i>J. Med. Chem.</i> , 32:788-792, 1989.
	C171	Divgi <i>et al.</i> , "Phase I and imaging trial of indium 111-labeled anti-epidermal growth factor receptor monoclonal antibody 225 in patients with squamous cell lung carcinoma," <i>J. National Cancer Institute</i> , 83(2):97-104, 1991.
	C172	Drobnik <i>et al.</i> , "Soluble synthetic polymers in biological systems," <i>Adv. Polym. Sci.</i> , 57:1-50, 1984.
	C173	Dunn <i>et al.</i> , "Receptor-mediated endocytosis of epidermal growth factor by hepatocytes in the perfused rat liver: ligand and receptor dynamics," <i>J. Cell Biol.</i> , 98:2148-2159, 1984.
	C174	Eary <i>et al.</i> , "Radiochemistry of halogenated antibodies," <i>Antibodies in Radiodiagnosis and Therapy</i> , Boca Ratan, Florida, CPC Press, 83-100, 1988.

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	C175	Eiseman <i>et al.</i> , "Plasma pharmacokinetics and tissue distribution of paclitaxel in CD2F1 mice," <i>Cancer Chemother. Pharmacol.</i> , 34:465-471, 1994.
	C176	Ennis <i>et al.</i> , "Anti-epidermal growth factor receptor antibodies inhibit the autocrine-stimulated growth of MDA-468 human breast cancer cells," <i>Mol. Endocrinology</i> , 3(11):1830-1838, 1989.
	C177	Ethier, "Growth factor synthesis and human breast cancer progression," <i>J. Natl. Cancer Inst.</i> , 87(13):964-973, 1995.
	C178	Fan <i>et al.</i> , "Antitumor effect of anti-epidermal growth factor receptor monoclonal antibodies plus cis-diamminedichloroplatinum on well established A431 cell xenografts," <i>Cancer Research</i> , 53:4637-4642, 1993.
	C179	Fan <i>et al.</i> , "Blockade of epidermal growth factor receptor function by bivalent and monovalent fragments of 225 anti-epidermal growth factor receptor monoclonal antibodies," <i>Cancer Research</i> , 53:4322-4328, 1993.
	C180	Fang <i>et al.</i> , "Involvement of p21 Waf1 in mediating inhibition of paclitaxel-induced apoptosis by epidermal growth factor in MDA-MB-468 human breast cancer cells," <i>Anticancer Research</i> , 20(1A):103-112, 2000.
	C181	Fidler <i>et al.</i> , "The biology of cancer invasion and metastasis," <i>Adv. Cancer Res.</i> , 28:149-250, 1987.
	C182	Foa <i>et al.</i> , "Taxol (paclitaxel): a novel anti-microtubule agent with remarkable anti-neoplastic activity," <i>J. Clin. Lab. Res.</i> , 24:6-14, 1994.
	C183	Frankel <i>et al.</i> , "Targeted toxins," <i>Clin. Cancer Res.</i> , 6:326-334, 2000.
	C184	Fuertges <i>et al.</i> , "The clinical efficacy of poly(ethylene glycol)-modified proteins," <i>J. Controlled Release</i> , 11:139-148, 1990.
	C185	Fuller <i>et al.</i> , "A procedure for the facile synthesis of amino-acid N-carboxyanhydride," <i>Biopolymers</i> , 15:1869, 1976.
	C186	Gabizon, "Selective tumor localization and improved therapeutic index of anthracyclines encapsulated in long-circulating liposomes," <i>Cancer Research</i> , 52:891-896, 1992.
	C187	Garipey <i>et al.</i> , "Vectorial delivery of macromolecules into cells using peptide-based vehicles," <i>Trends in Biotechnology</i> , 19(1):21-28, 2001.

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	C188	Girard, "Mechanisms by which carbohydrates regulate expression genes for clycolytic and lipogenic enzymes," <i>Ann. Rev. Nutr.</i> , 17:325-352, 1997.
	C189	Goldenberg <i>et al.</i> , "Imaging of human tumor xenografts with and indim-111-labeled anti-epidermal growth factor receptor monoclonal antibody," <i>J. National Cancer Institute</i> , 81:1616-1625, 1989.
	C190	Goldenberg, "Monoclonal antibodies in cancer detection and therapy," <i>Am. J. Med.</i> , 94:297-312, 1993.
	C191	Goldspeil, "Pharmaceutical issues: preparation, administration, stability, and compatibility owth other medications," <i>Ann. Pharcother.</i> , 28:S23-S26, 1994.
	C192	Gonda, "Aerosols for delivery of therapeutic and diagnostic agents to the respiratory tract," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 6(4):273-313, 1990.
	C193	Greenfield <i>et al.</i> , "In vitro evaluation of immunoconjugates prepared by linking mitomycin C to monoclonal antibodies via polyglutamic acid carriers," <i>Antibody, Immunoconjugates, and Radiopharmaceuticals</i> , 2(3):201-216, 1989.
	C194	Greenwald <i>et al.</i> , "Drug delivery systems: water soluble tazol 2'-poly(ethylene glycol) ester prodrugs-design and in vivo effectiveness," <i>J. Med. Chem.</i> , 39:424-431, 1996.
	C195	Halpern <i>et al.</i> , "Stability, characterization, and kinetics of In-labeled monoclonal antitumor antibodies in normal animals and nude mouse human tumor models," <i>Cancer Research</i> , 43:5347-5355, 1983.
	C196	Hermanson, "Amine detection reagents," <i>Bioconjugate Techniques</i> , San Diego, Academic Press, 112-114, 1996.
	C197	Hermanson, "Ellman's assay for the determination of sulfhydryls," <i>Bioconjugate Techniques</i> , Sand Diego, Academic Press, 88-90, 1996.
	C198	Hnatowich <i>et al.</i> , "Radioactive labeling of antibody: a simple and efficient method," <i>Science</i> , 220:613-615, 1983.
	C199	Hoes <i>et al.</i> , "Optimization of macromolecular prodrugs of the antitumor antibiotic adriamycin," <i>J. Controlled Release</i> , 2:205-213, 1985.

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	C201	Hudecz <i>et al.</i> , "Influence of carrier on biodistribution and in vitro cytotoxicity of methotexate-branched polypeptide conjugates," <i>Bioconjugate Chemistry</i> , American Chemical Society, 4(1):25-33, 1993.
	C202	Inoue <i>et al.</i> , "Paclitaxel enhances the effects of the anti-epidermal growth factor receptor monoclonal antibody ImClone C225 in mice with metastatic human bladder transitional cell carcinoma," <i>Clinical Cancer Res.</i> , 6:4874, 4884, 2000.
	C203	Irie <i>et al.</i> , "Regression of cutaneous metastatic melanoma by intralesional injection with human monoclonal antibody to ganglioside GD2," <i>Proc. Natl. Acad. Sci., USA</i> , 83:8694-8698, 1986.
	C204	Jeppesen <i>et al.</i> , "Impact of polymer tether length on multiple ligand-receptor bond formation," <i>Science</i> , 293:465-468, 2001.
	C205	Jurisson <i>et al.</i> , "Potential technetium small molecule radiopharmaceuticals," <i>Chem. Rev.</i> , 99:2205-2218, 1999.
	C206	Kato and Sugiyama, "Targeted delivery of peptides, proteins, and genes by receptor-mediated endocytosis," <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , 14(3):287-331, 1997.
	C207	Kato <i>et al.</i> , "A novel method of conjugation of daunomycin with antibody with a poly-L-glutamic acid- $\alpha$ -fetoprotein antibody-daunomycin conjugate," <i>J. Med. Chem.</i> , 27:1602-1607, 1984.
	C208	Kitamura <i>et al.</i> , "Chemical engineering of the monoclonal antibody A7 by polyethylene glycol for targeting cancer chemotherapy," <i>Cancer Research</i> , 51:4310-4315, 1991.
	C209	Klok <i>et al.</i> , "Star-shaped fluorescent polypeptides," <i>Journal of Polymer Science</i> , 39(10):1572-1582, 2001.
	C210	Kopecek <i>et al.</i> , "Targetable water-soluble polymeric anticancer drugs: achievements and unsolved problems," <i>Proc. Intern. Symp. Control. Rel. Bioact. Mater.</i> , 20:190-191, 1993.
	C211	Kopecek <i>et al.</i> , "Targetable polymeric prodrugs," <i>J. Control. Release</i> , 6:315-327, 1987.
	C212	Kopecek, "The potential of water-soluble polymeric carriers in targeted and site-specific drug delivery," <i>Journal of Controlled Release</i> , 11:279-290, 1990.

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List of Patents and Publications for Applicant's

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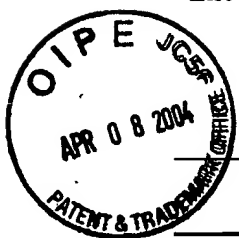
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